DOES HIPAA APPLY?

GENERAL RULE: "Except as otherwise provided in this part, if a covered entity conducts with another covered entity (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction." (45 CFR 162.923(a))

IS IT A COVERED ENTITY?

Is it a health plan?

- Health plans include the following:

  → Individual or group plan that provides, or pays the cost of, medical care.[1]

  → A group health plan.[2]

  → A health insurance issuer.[3]

  → An HMO.[4]

  → Part A or Part B of the Medicare program.[5]

  → The Medicaid program.[6]

  → An issue of a Medicare supplemental policy.[7]

  → An issuer of a long-term care policy, excluding a nursing home fixed indemnity policy.

  → An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.

  → The health care program for active military personnel under title 10 of the United States Code.

→ The veterans health care program.[8]

→ The Civilian Health and Medical Program of the Uniformed Services.[9]

→ The Indian Health Service program under the Indian Health Care Improvement Act.[10]

→ The Federal Employees Health Benefit Program.[11]

→ An approved state child health plan providing required benefits.[12]

→ The Medicare + Choice program.[13]

→ Any other individual or group plan, that provides or pays for the cost of medical care.[14]

- When applied to government funded programs, the regulations apply to the components of the government agency administering the program.

- The following are not considered health plans, unless specifically identified as a health plan above:

  → Any policy, plan, or program to the extent that it provides, or pays for the cost of, certain excepted benefits.[15]

  → Any government-funded program (other than one listed above) whose principal purpose is other than providing, or paying the cost of health care.[16]

  → Any government-funded program (other than one listed above) whose principal activity is the direct provision of health care to persons.[17]

  → Any government-funded program (other than one listed above) whose principal activity

is the making of grants to fund the direct provision of health care to persons.

Is it a health care clearinghouse?

- A public or private entity[18] that processes or facilitates the processing of information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.

- A public or private entity that receives a standard transaction from another entity and processes or facilitates the processing of information into nonstandard format or nonstandard data content for a receiving entity.

- A department or component of a health plan or health care provider that transforms nonstandard information into standard data elements or standard transactions (or vice versa) is not a clearinghouse for purposes of this rule, unless it also performs these functions for another entity.

- Affiliates[19] may perform clearinghouse functions for each other without becoming “clearinghouses” within the meaning of HIPAA.

Is it a health care provider who transmits any health information in electronic form in connection with a transaction covered by the regulations?

- Health care provider means:

  → A provider of services.[20]

  → A provider of medical or other health services.[21]

  → Any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

- Health care providers cannot circumvent the application of the rule where another entity (e.g. a hospital or billing service) transmit standard electronic transactions on their behalf.

IS THE INFORMATION TRANSMITTED BY ELECTRONIC MEDIA?

- "*Electronic media* means the mode of electronic transmission. It includes the Internet (wide-open). Extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media." (45 C.F.R. 162.103.)

IS IT A STANDARD TRANSACTION?

Is it a transaction?

- Exchange of information between two parties to carry out financial or administrative activities related to health care.

- Includes the following:

  → Health care claims or equivalent encounter information.

  → Health care payment and remittance advice.

  → Coordination of benefits.

  → Health care claim status.

  → Enrollment and disenrollment in a health plan.

  → Eligibility for a health plan.

  → Health plan premium payments.

  → Referral certification and authorization.

→ First report of injury.

→ Health claims attachments.

→ Other transactions that the Secretary may prescribe by regulation.

Is it subject to a standard?

- Standard is defined as “a prescribed set of rules, conditions, or requirements describing the following information for products, systems, services or practices: (1) Classification of components. (2) Specification of materials, performance, or operations. (3) Delineation of procedures.”

ARE OTHER ENTITES EFFECTED?

Business associates: A covered entity that uses a business associate must require the business associate to comply with HIPAA and require that the business associate’s agents or subcontractors comply with HIPAA.

- A person who performs a function or activity involving the use or disclosure of individually identifiable health information.

- A person who performs any function or activity regulated by the HIPAA regulations.

- A person who provides legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to of for a covered entity, or for an organized health care arrangement in which the covered entity participates, where the provision of the services involves the disclosure of individually identifiable health information from the covered entity or arrangement, or from another business associate of the covered entity or arrangement, to the person.

- Excludes persons who are part of the covered entity’s workforce.[22]

- Joint administration of a health plan by two public entities or a public and private entity does not meet the definition of a business associate. Examples include, state and federal administration of the Medicaid and SCHIP program, or joint administration of a Medicare+Choice plan by the Health Care Financing Administration and the issuer offering the plan.

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[1] *See* 42 U.S.C. 300gg–91(a)(2) ("The term ''medical care'' means amounts paid for—

(A) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,

(B) amounts paid for transportation primarily for and essential to medical care referred to in subparagraph (A), and

(C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).").

[2] *See* 45 C.F.R. 160.103 ("*Group health plan* (also see definition of *health plan* in this section)means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income and Security Act of 1974 (ERISA), 29 U.S.C. 1002(1)), including insured and self-insured plans, to the extent that the plan provides medical care (as defined in section 2791(a)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 300ggg–91(a)(2)), including items and services paid for as medical care, to employees or dependents directly or through insurance, reimbursement, or otherwise that: (1) Has 50 or more participants (as defined in section 3(7) of ERISA, 29 U.S.C. 1002(7)); or (2) Is administered by an entity other than the employer that established and maintains the plan.").

[3] *See* 45 C.F.R. 160.103 ("*Health insurance issuer* (as defined in section 2791(b)(2) of the PHS Act, 42 U.S.C. 300–gg91(b)(2) and used in the definition of *health plan* in this section) means an insurance company, insurance service, or insurance organization (including an HMO) that is licensed to engage in the business of insurance in a State and is subject to State law that regulates insurance. Such term does not include a group health plan.").

[4] *See* 45 C.F.R. 160.103 ("*Health maintenance organization* (HMO) (as defined in section 2791(b)(3) of the PHS Act, 42 U.S.C. 300gg–91(b)(3) and used in the definition of *health plan* in this section) means a federally qualified HMO, an organization recognized as an HMO under State law, or a similar organization regulated for solvency under State law in the same manner and to the same extent as such an HMO.").

[5] *See* 42 U.S.C. 1395c *et seq.* (Part A) and 42 U.S.C. ___ 1395j *et seq.* (Part B).

[6] *See* 42 U.S.C. 1396 *et seq*. The commentary to the regulations provides the following explanation: "We note that in certain instances eligibility for or enrollment in a health plan that is a government program providing public

benefits, such as Medicaid or SCHIP, is determined by an agency other than the agency that administers the program, or individually identifiable health information used to determine enrollment or eligibility in such a health plan is collected by an agency other than the agency that administers the health plan. In these cases, we do not consider an agency that is not otherwise a covered entity, such as a local welfare agency, to be a covered entity because it determines eligibility or enrollment or collects enrollment information as authorized by law. We also do not consider the agency to be a business associate when conducting these functions, as we described further in the business associate discussion above." (65 Fed. Reg. No. 250 (Dec. 28, 2000) 82478.)

[7] *See* 42 U.S.C. 1395ss(g)(1) ("For purposes of this section, a medicare supplemental policy is a health insurance policy or other health benefit plan offered by a private entity to individuals who are entitled to have payment made under this subchapter, which provides reimbursement for expenses incurred for services and items for which payment may be made under this subchapter but which are not reimbursable by reason of the applicability of deductibles, coinsurance amounts, or other limitations imposed pursuant to this subchapter; but does not include or a Medicare+Choice plan or any such policy or plan of one or more employers or labor organizations, or of the trustees of a fund established by one or more employers or labor organizations (or combination thereof), for employees or former employees (or combination thereof) or for members or former members (or combination thereof) of the labor organizations and does not include a policy or plan of an eligible organization (as defined in section 1395mm(b) of this title) if the policy or plan provides benefits pursuant to a contract under section 1395mm of this title or an approved demonstration project described in section 603(c) of the Social Security Amendments of 1983, section 2355 of the Deficit Reduction Act of 1984, or section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, or a policy or plan of an organization if the policy or plan provides benefits pursuant to an agreement under section 1395l(a)(1)(A) of this title. For purposes of this section, the term ''policy'' includes a certificate issued under such policy.")

[8] 38 U.S.C. Chapter 17.

[9] 10 U.S.C. 1072(4) (defined).

[10] 25 U.S.C. 1601 *et seq*.

[11] 5 U.S.C. 8902 *et seq*.

[12] 42 U.S.C. 1397 *et seq*.

[13] 42 U.S.C. 1395w-21 through 1395w-28.

[14] See Endnote 1, *supra*.

[15] *See* 42 U.S.C. 300gg—91(c)(1) ("(1) Benefits not subject to requirements
(A) Coverage only for accident, or disability income insurance, or any combination thereof.
(B) Coverage issued as a supplement to liability insurance.
(C) Liability insurance, including general liability insurance and automobile liability insurance.
(D) Workers' compensation or similar insurance.

(E) Automobile medical payment insurance.
(F) Credit-only insurance.
(G) Coverage for on-site medical clinics.
(H) Other similar insurance coverage, specified in regulations, under which benefits for medical care are secondary or incidental to other insurance benefits.”).

[16] Examples of programs that incidentally provide health services but which are not health plans include Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and the Food Stamp Program.

[17] Examples of programs that have as their direct purpose the provision of health care but which do not constitute health plans include the Ryan White Comprehensive AIDS Resources Emergency Act, government funded health centers and immunization programs.

[18] Entities include but are not limited to, billing services, repricing companies, community health management information systems or community health information systems and ‘value-added’ networks and switches.

[19] Affiliates are legally separate covered entities that designate themselves as a single covered entity, if all of the designated entities are under common ownership or control and if the designation is properly documented. (45 C.F.R. 164.504(d).)

[20] 42 U.S.C. 1395x(u) (“The term ''provider of services'' means a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, or, for purposes of section 1395f(g) and section 1395n(e) of this title, a fund.”).

[21] 42 U.S.C. 1395x(s) (“The term ''medical and other health services'' means any of the following items or services:
(1) physicians' services;
(2)(A) services and supplies (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills;
(B) hospital services (including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered) incident to physicians' services rendered to outpatients and partial hospitalization services incident to such services;
(C) diagnostic services which are -
(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and
(ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients for the purpose of diagnostic study;
(D) outpatient physical therapy services and outpatient occupational therapy services;
(E) rural health clinic services and Federally qualified health center services;
(F) home dialysis supplies and equipment, self-care home

dialysis support services, and institutional dialysis services and supplies;

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in subsection (r)(1) of this section, for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

(H)(i) services furnished pursuant to a contract under section 1395mm of this title to a member of an eligible organization by a physician assistant or by a nurse practitioner (as defined in subsection (aa)(5) of this section) and such services and supplies furnished as an incident to his service to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service; and

(ii) services furnished pursuant to a risk-sharing contract under section 1395mm(g) of this title to a member of an eligible organization by a clinical psychologist (as defined by the Secretary) or by a clinical social worker (as defined in subsection (hh)(2) of this section), and such services and supplies furnished as an incident to such clinical psychologist's services or clinical social worker's services to such a member as would otherwise be covered under this part if furnished by a physician or as an incident to a physician's service;

(I) blood clotting factors, for hemophilia patients competent to use such factors to control bleeding without medical or other supervision, and items related to the administration of such factors, subject to utilization controls deemed necessary by the Secretary for the efficient use of such factors;

(J) prescription drugs used in immunosuppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this subchapter, but only in the case of drugs furnished -

(i) before 1995, within 12 months after the date of the transplant procedure,

(ii) during 1995, within 18 months after the date of the transplant procedure,

(iii) during 1996, within 24 months after the date of the transplant procedure,

(iv) during 1997, within 30 months after the date of the transplant procedure, and

(v) during any year after 1997, within 36 months after the date of the transplant procedure;

(K)(i) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a physician assistant (as defined in subsection (aa)(5) of this section) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service; but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services, and

(ii) services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1) of this section) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5) of this section) working in collaboration (as defined in subsection (aa)(6) of this section) with a physician (as defined in subsection (r)(1) of this section) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services and supplies furnished as an incident to such services as would be covered under subparagraph (A) if furnished incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

(L) certified nurse-midwife services;

(M) qualified psychologist services;

(N) clinical social worker services (as defined in subsection (hh)(2) of this section);

(O) erythropoietin for dialysis patients competent to use such drug without medical or other supervision with respect to the administration of such drug, subject to methods and standards established by the Secretary by regulation for the safe and effective use of such drug, and items related to the administration of such drug;

(P) prostate cancer screening tests (as defined in subsection (oo) of this section);

(Q) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an anticancer chemotherapeutic agent for a given indication, and containing an active ingredient (or ingredients), which is the same indication and active ingredient (or ingredients) as a drug which the carrier determines would be covered pursuant to subparagraph (A) or (B) if the drug could not be self-administered;

(R) colorectal cancer screening tests (as defined in subsection (pp) of this section); and

(S) diabetes outpatient self-management training services (as defined in subsection (qq) of this section); and

(T) an oral drug (which is approved by the Federal Food and Drug Administration) prescribed for use as an acute anti-emetic used as part of an anticancer chemotherapeutic regimen if the drug is administered by a physician (or as prescribed by a physician) -

(i) for use immediately before, at, or within 48 hours after the time of the administration of the anticancer chemotherapeutic agent; and

(ii) as a full replacement for the anti-emetic therapy which would otherwise be administered intravenously;

(3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act (42 U.S.C. 263b)), diagnostic laboratory tests, and other diagnostic tests;

(4) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians;

(5) surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations;

(6) durable medical equipment;

(7) ambulance service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations;

(8) prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens;

(9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;

(10)(A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and

(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb) of this section);

(12) subject to section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, extra-depth shoes with inserts or custom molded shoes with inserts for an individual with diabetes, if -

(A) the physician who is managing the individual's diabetic condition (i) documents that the individual has peripheral neuropathy with evidence of callus formation, a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and (ii) certifies that the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition;

(B) the particular type of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary); and

(C) the shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician described in subparagraph (A) (unless the Secretary finds that the physician is the only such qualified individual in the area);

(13) screening mammography (as defined in subsection (jj) of this section);

(14) screening pap smear and screening pelvic exam; and

(15) bone mass measurement (as defined in subsection (rr) of this section).

No diagnostic tests performed in any laboratory, including a laboratory that is part of a rural health clinic, or a hospital (which, for purposes of this sentence, means an institution considered a hospital for purposes of section 1395f(d) of this title) shall be included within paragraph (3) unless such

laboratory -

(16) if situated in any State in which State or applicable local law provides for licensing of establishments of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing establishments of this nature, as meeting the standards established for such licensing; and

(17)(A) meets the certification requirements under section 353 of the Public Health Service Act (42 U.S.C. 263a); and

(B) meets such other conditions relating to the health and safety of individuals with respect to whom such tests are performed as the Secretary may find necessary.

There shall be excluded from the diagnostic services specified in paragraph (2)(C) any item or service (except services referred to in paragraph (1)) which would not be included under subsection (b) of this section if it were furnished to an inpatient of a hospital. None of the items and services referred to in the preceding paragraphs (other than paragraphs (1) and (2)(A)) of this subsection which are furnished to a patient of an institution which meets the definition of a hospital for purposes of section 1395f(d) of this title shall be included unless such other conditions are met as the Secretary may find necessary relating to health and safety of individuals with respect to whom such items and services are furnished.").

[22] Persons working at a covered entity's work station on the covered entity's premises and who perform a substantial proportion of their activities at that location may be considered workforce members by the covered entity. Absent a business associate agreement, they will be assumed to be members of the covered entity's workforce, as will independent contractors. (65 Fed. Reg. 250 (Dec. 28, 2000) 82480.)